STATEMENT BY

FRANK E. YOUNG, M.D., Ph.D.

FORMER COMMISSIONER
FOOD AND DRUG ADMINISTRATION
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Introduction:

Thank you, Chairman Waxman and Mr. Davis, for the opportunity to testify before you today. My name is Frank E. Young, M.D., Ph.D. I served as Commissioner of the FDA from July 7, 1984 to December 12, 1989 and remained in the Department of Health and Human Services serving as Deputy Assistant Secretary for Health, Science and Environment (1989-1993) and as Director of the Office of Emergency Preparedness and the National Disaster Medical System with concurrent responsibility for Emergency Support Function (ESF 8) under FEMA's Emergency Response Plan from 1993-1996 and representative of DHHS on the Council of Deputies of the National Security Council (1993-1996). My testimony is based on 12 years of government service. I appreciate the opportunity to discuss the future of FDA, an agency that is vital to the well being of our citizens.

FDA has long enjoyed a reputation as one of the most important, trustworthy, and effective regulatory agencies in the United States. Indeed, FDA is heralded as the gold standard among public health regulatory bodies around the world. Regrettably, the agency's reputation is suffering as FDA's recent performance has been compromised by: neglect due to short term Commissioners; a work load that greatly outstrips its resources; accelerating technological challenges coupled with insufficient resources to remain at the forefront of the science it regulates; a crush of imported goods with an insufficient number of enforcement personnel; and an ever increasing degree of political influence in what should be a scientifically based agency. FDA is wounded! The agency requires more than a bandage of additional resources as important as they are! It needs, in fact the public should demand, a careful diagnosis and appropriate therapy that is both safe for the many outstanding professionals in the agency and those in the global community that depend on it and effective in restoring it to its previous healthy state. Only a robust FDA can assure the safety and effectiveness of new drugs and biologics, the safety and utility of new devices, the proper registration of cosmetics, ensure the safety of our food supply and prepare for the impact of the genomic revolution on new foods. Recently, the animal health of our pets has been threatened by contamination of the pet food that our consumers bought in good conscience. This flaw illustrates of particular importance is the effective regulation of imported products, as we exist in an ever growing global economy. Our public needs a uniform safety standard for imported and domestic products. Sufficient resources are required for both FDA inspectors and FDA regional labs that support them.

I congratulate the committee for holding this hearing aimed at remedying the current debilitated state of the agency. Here are a number of observations to facilitate your diagnosis. These will be followed by some recommendations for treatment.

1. Leadership FDA has had substantial periods of time under the leadership of acting commissioners and short term commissioners. The agency is partially paralyzed by this revolving door syndrome. Strong and sustained stable leadership is required to gain the trust of the agency and the nation. Accordingly, it is recommended that the commissioner be appointed for a 6 year term and subject to removal only for malfeasance or non professional behavior.

2. Commissioner Recruitment: All commissioners after my tenure have been Senate confirmed. The past practice of suggesting candidates to the Secretary through a search committee composed of health professionals familiar with the functions of the agency has been abandoned. It is recommended that the process be less political and that the Commissioner have expertise in some of the areas regulated by FDA. More independence from both Administration and Congressional political agendas is required to ensure that the public health needs that are critical to the well-being of the nation are met based on science. For example, Secretary Heckler recruited me to address the biotechnology revolution. My background was in rDNA and, before joining FDA, I had attended the Asilomar meeting and was a charter member of the NIH Recombinant DNA Committee (RAC). I was charged by the Secretary, among other things, to develop an action plan to renew the agency and to focus on the regulations for the safe development of rDNA drugs, biologics and diagnostic reagents. During my tenure the number of approved products in the field increased from 4 to over 10,000 and the national and international guidelines for the safe use of these products were developed and implemented by staff within the FDA.

Now, as noted in a speech by former Commissioner McClellan [1] at Harvard, the field of genomics is likely to impact foods in a similar fashion to the eighties when the influence of rDNA on biologics, drugs and diagnostics introduced new regulatory scientific and safety considerations. As this field progresses, and the line between foods and drugs becomes blurred, there will be a need for careful regulatory delineation. These advances in technology require that both the Commissioner and the staff of FDA be scientifically competent. Thus, an environment to scientific inquiry as well as resources is essential. Sound regulation in new and expanding fields is built on a foundation of sound science.

3. Scientific Expertise: There has been a major erosion of the scientific expertise within the FDA. Research in the Center for Biologic Evaluation and Research has been eviscerated through the recent reorganization and is almost non-existent in the Center for Drug Evaluation and Research. To maintain the expertise necessary for expeditious but highly competent decisions on new breakthrough products, and to have the proper knowledge to evaluate potential safety problems in foods, biologics, drugs and animal biologics and drugs as well as the knowledge to evaluate new devices, it is essential to have a well trained scientific staff that is given the time to not only maintain scientific expertise but to pursue career development in their chosen field of science. It is also necessary for these scientists to be able to express their opinions freely but to appreciate that when a decision arrived at through careful scientific investigation and consensus is reached, that Agency policy will be implemented. Therefore, recruitment and retention

[1] On July 1, 2003 former Commissioner McClellan noted "it's quite possible that, within the next decade or two, genomics will not only provide many valuable insights into the development of highly effective, individualized medical treatments; it may also give us the knowledge we need to understand which foods may be particularly risky or beneficial for particular persons, so that we can make specific, individualized adjustments in our diets to prevent some serious diseases. There is a small but growing field called "nutrigenomics" that is seeking to combine the increasing insights from genomics to our understanding of how dietary choices affect our health."

of outstanding scientists must be redressed through staff expansion and provision of time for professional development including, as appropriate, laboratory research. This applies not only to drugs and biologics but to all aspects of foods as well. The genomic and proteomic revolution as well as regenerative cellular therapies and devices that will reduce the burden of disease require a highly skilled staff in order to reach sound regulatory decisions.

4. Evaluation process: There is a substantial problem in the biologic and drug evaluation process. The certainty and predictability of the process needs to be improved. There have been layers upon layers of Congressional mandates and Administration-led regulations that have grown like onion rings with each new administration. Not only should the cost of medicines be reduced through competitive processes (such as the generic drug initiative) but the cost of development needs to be reassessed through a comprehensive overhaul of the product review process, including the phase 4 process. An unpredictable regulatory process complicated by high staff turnover inevitably leads to a greater cost of the development of new therapies and stifles innovation of new drugs and biologics. I already detect a shift in the market place of investments to favor devices over drugs and an emphasis on later stage investments to reduce the uncertainty in return on investment. The erosion of innovation and entrepreneurial leadership in the United States needs to be stopped through a compressive review of the process for product review. The last comprehensive of the drug evaluation occurred during my tenure over 20 years ago (the IND and NDA re-writes). Furthermore, although I suggested the implementation of user fees while I was Commissioner and Senator Hatch introduced the first User fee bill, the implementation of user fees has resulted in a substantial reduction in other areas of the agency's budget. It is important to remember that the user fees were initiated out of desperation. It is proposed that Congress carefully weigh the proportion of funds allotted to user fees and appropriated funds.

5. Safety of Drugs and Biologics: The evaluation of safety of drugs and biologics has been reduced by the strict provisions of the user fee legislation (Prescription Drug User Fee Act; PDUFA) and reductions of the core sections of the agency budget. While I strongly favor appropriate levels of funding of FDA's budget to develop a well financed and properly staffed office for drug and biologic safety within FDA, current financial constraints within FDA due to budgetary imbalances between appropriated and PDUFA funds led to a compromise of the drug safety program and precluded a comprehensive analysis of drug safety. The history of the FDA demonstrates that major legislation follows crises within the FDA regulated products. The initial revision in 1938 was due to the use of ethylene glycol as a solvent for Elixir Sulfanilamide resulting in the death of 107 people and the Kefauver-Harris Drug Act of 1962, which required that new drugs must be shown to be both safe and effective followed the thalidomide crisis. Rather than waiting for each new crisis, such as the current problem stemming from the Vioxx recall, there must there be a comprehensive analysis of drug safety. For example, it is difficult to obtain a comprehensive analysis of safety of new drugs due to infrequent events based on the study a few thousand patients in phase 3. Yet, it is inappropriate to study tens of thousands of patients during the NDA studies, as it would unnecessarily prolong the evaluation process. It must be emphasized that all new drugs and biologics present a

risk-benefit equation as no new chemical or biological drug is absolutely safe. Therefore, comprehensive safety analysis should be performed through active post-market surveillance. Ideally these studies can be financed by appropriated funds. I favor this approach. If Congress deems that such monies are not available within the appropriation budget, there may be another mechanism of ensuring drug and biologic safety through privatization of the process but under FDA oversight. For example, a fee of $0.05 per script could be collected and pooled to be used to evaluate the safety of marketed drugs and biologics. FDA would have the responsibility of selecting the products for review annually, based on a risk-benefit assessment following the NDA approval and establishing the review process, but the analysis could be undertaken by the appropriate private sector organization. While I personally strongly favor an appropriated process and a staffing of the effort within FDA, as it spreads the burden more equitably and retains complete oversight functions within the FDA, the need for a comprehensive safety program is of sufficient magnitude that we must, as a nation, find a solution.

6. Appropriations and Oversight: Examination of the appropriations process reveals a major anomaly. The Agency charged with the protection of the drug and biologic supply of our citizens, the security of the blood supply and the tissue and cellular products and the complex devices that are implanted in our body like pacemakers and artificial joints is funded through the Agriculture Committee. It is essential that we have a sound national agricultural appropriations process, but I submit that funding a medically based regulatory agency through a committee that primarily funds agriculture is as silly as funding the defense budget through a Labor and Health Committee. Congress can readily abolish this anomaly if it has the will! I strongly recommend that Congress undertake this politically courageous action. At the same time Congress should, in my opinion, re-examine the overlapping committee structure that has oversight of FDA functions and consolidate them into fewer committees.

7. Inter-agency coordination: The public health inter-agency coordination is effete and ineffectual. In the 1990's the role of the office of the Assistant Secretary of Health in coordinating public health policy was markedly reduced. Instead of bi-weekly meetings of the public health agency heads led by a medically qualified Assistant Secretary who could coordinate the solution of pressing public health problems and develop interactive budgets, the coordination is now greatly diminished and primarily occurs at the more political secretarial level. This results in less harmonized and less expeditious development of public health policies. I recommend that the responsibility for ensuring coordination of the public health agencies be re-examined.

8. Inspection: The FDA's inspection personnel and regional laboratories are inadequate to ensure that the same high standard in quality applies to both domestic and imported products sold to the American public. In my opinion, there are substantial inequities between the regulation of domestic industry and the foreign industries.. Because the level of inspections of imported products is so low, it is better for the importers to have

goods seized as the cost of doing business, rather than to comply with FDA standards. A comprehensive needs analysis for ensuring a level playing field needs to be undertaken.

9. **Unfunded Mandates:** New Congressionally mandated programs are frequently mandated without resources for adequate implementation—instead, they need to be adequately resourced. While I was Commissioner there were mandates for 22 new activities without accompanying appropriations. If the program cannot be funded, the agency should not receive the additional responsibility. Congress is currently considering generic versions of biological drugs (called follow-on biologics). The establishment of such a major new program requires care and adequate resources For example, I can attest to the difficulty the agency faced in the initial implementation of the Hatch Waxman Act for the expeditious evaluation of generic drug products. Because the financial rewards for industry were so great, there were major problems in the development of procedures within FDA, inadequate resources available for crafting the regulations, and difficulties in the implementation of the initial ANDA review processes. Similarly, there were substantial budgetary needs for adequate enforcement of procedures for approval of products developed by industry during the initial implementation of the act. The agency was in uncharted waters. Nevertheless, with time and agency experience, this legislation was successful although some questions about bioequivalency and safety persist. Now, almost 50% of the prescriptions are for generic drugs. Great care will be required to craft the legislation and regulations for follow-on biologics if they are deemed appropriate. Particular attention will be needed to ensure that the agency has sufficient qualified scientific personnel and the required resources to ensure safe and effective follow on biologics. These compounds are proteins with more complex structures and substituents. The task establishment of similarity is very difficult.

Conclusion: Based on my career of 12 years in DHHS serving as Commissioner of FDA, Deputy Assistant Secretary of Health, Science and Environment and Director of the Office of Emergency Preparedness, I can attest to the dedication and expertise of most of the employees within what used to be an integrated Public Health Service. We need to give these professionals the tools, continuing education and a constant stream of new professionals which are the life blood of the FDA. Before the posturing of election politics gets into full swing, it is time to lay the foundation of a revitalized FDA in a bipartisan fashion. I am pleased to see this committee address such a task.

I hope these observations and recommendations will assist you as you focus on the revitalization of FDA, an agency that is so essential to the protection and enhancement of health in our nation. I strongly recommend that you carefully evaluate the budgetary proposals of the FDA Alliance and the Coalition for a Stronger FDA that recommended resources to support these initiatives.

Thank you for your attention. I shall be pleased to respond to your questions.